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510(k) Summary

Regulatory Affairs Contact:	Muhamad Ansari Busse Hospital Disposables PO Box: 11067 75 Arkay Dr. Hauppauge NY 11788
Telephone:	631-435-4711 Ext: 254
Fax:	631-435-2849
Date Summary Prepared:	March 25, 2011
Product Trade Name:	J-Style Bone Marrow Biopsy / Aspiration Needle with Snare-It Acquisition Cannula
Common Name:	Biopsy Instrument
Classification Name:	Class II, 21 CFR 876.1075, Product code KNW
Predicate Device:	Osteobell Bone Marrow Biopsy Needle
Device Description:	The J-Style Bone Marrow Biopsy / Aspiration Needle with Snare-It Marrow Acquisition Cannula consists of a J-style Bone Marrow Biopsy / Aspiration Needle with cap, providing the physician with greater torque than similar instruments, an ABS Ergonomic grip handle, which increases accuracy and speeds biopsy operation. It comes in 3 sizes; 8G x 4", 11G X 4", and 13G x 4". A Stylet, consisting of a locking mechanism to secure position in Biopsy needle, as well as a stainless steel cannula with a trocar tip for easier penetration into bone tissue. The Snare-It Marrow Acquisition Cannula is designed to allow the tissue to remain intact during removal. This allows for accurate analysis. It also allows additional sample collection without having to re-insert needle into the patient. A stainless steel, sample extractor, allows for convenient sample removal from the cannula. And finally, an extractor Cap.

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Intended Use:

This Biopsy Instrument is used for drawing of osteomedullary substance or for explantation of bone marrow with a Snare-It Acquisition Cannula intended to contain the specimen during withdrawal from the needle's cannula.

Technological Characteristics:

The subject device has the same Technological Characteristics as a legally marketed predicate device.

Summary of Testing:

All materials used in the fabrication of the J-Style Bone Marrow Biopsy / Aspiration Needle with Snare-It Acquisition Cannula were evaluated through biological qualification safety tests.
The biocompatibility tests performed were:

- Cytotoxicity Test
- Intracutaneous Reactivity Test

These materials have met the testing requirements and were found to be acceptable for the intended use.

Conclusion:

The above statements are accurate representations of the device Busse intents to market. Based on all the testing and comparison Busse believes the subject device is substantially equivalent to the predicate device. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Busse Hospital Disposables
% Mr. Muhamad Ansari
P.O. Box 11067
75 Arkay Drive
Hauppauge, New York 11788

JUN - 8 2011

Re: K110883
Trade/Device Name: J-Style Bone Marrow Biopsy/Aspiration Needle with Snare-it Marrow Acquisition Cannula
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: March 25, 2011
Received: March 30, 2011

Dear Mr. Ansari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

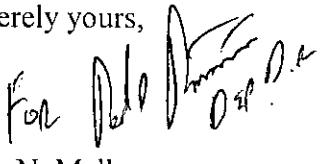
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K110883

Device Name: **J-Style Bone Marrow Biopsy / Aspiration Needle with Snare-It Marrow Acquisition Cannula**

This biopsy instrument is used for drawing of osteomedullary substance or for explantation of bone marrow with a Snare-It Marrow Acquisition Cannula intended to contain the specimen during withdrawal from the needle's cannula.

Prescription Use ___X___ (Per 21 CFR 801.109) OR Over-The-Counter Use_____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Nilay P. Patel for mxm

vision Sign-Off)
sion of Surgical, Orthopedic,
Restorative Devices

510(k) Number K110883